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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,499	02/23/2004	Hsiao Ching-fen	7257/72013	2138

7590 06/03/2005

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,499	CHING-FEN ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Declaration under 37 CFR 1.132 filed 03/04/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While applicant's specification at page 4, lines 22-23 discloses the concentration of tamsulosin in the sustained release formulations is from *about* 0.03% to *about* 3% by weight, the claims recite "0.03% to 3% by weight. It appears that applicant's specification does not provide specific guidance of the exact amount being recited in the claims, which is precisely 0.03% to precisely 3% by weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaghefi et al. US 2003/0157326 A1, in view of Platteeuw US 2005/0106253 A1.

Vaghefi teaches a sustained release microspheres comprising active agent, water insoluble matrix material comprising a pH insensitive material, from about 0.5% to about 30% disintegrating agent, from about 0.2% to about 20% lubricant (see abstract, and paragraphs 0100-0104). Active agent includes tamsulosin (page 10, column 1, line 2); pH insensitive material includes ethyl cellulose, cellulose acetate, hydrogenated vegetable oil, and waxes in an amount of from 100% to about 10% (paragraphs 0057 and 0060); disintegrating agent includes microcrystalline cellulose, starch, sodium starch glycolate, and crosscarmellose sodium; and lubricant includes carnauba wax, and glyceryl behenate (paragraphs 0101-0103).

Vaghefi does not teach the claimed amount of tamsulosin.

Platteeuw teaches a pharmaceutical composition comprising from 0.05 to 5% of tamsulosin or salt thereof (paragraphs 0010 and 0024). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release formulation of Vaghefi using the amount of tamsulosin in view of the teaching of Platteeuw to obtain the claimed invention, because Vaghefi teaches the amount of bioactive compound comprising in the composition will depend on various factors, including, for example, the particular bioactive compound used, and because Platteeuw teaches sustained release pellets composition for the specific bioactive compound, namely, tamsulosin in an effective amount useful for the condition to be treated.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukui et al. US 4,772,475.

Fukui teaches a controlled release formulation comprising as active agent an α-blocking agent 5-[2-[2-(o-ethoxyphenoxy)ethylamino]propyl}-2-methoxybenzenesulfonamide (tamsulosin), crystalline cellulose, and release controlling agent (abstract, column 3, lines 3-42; and column 4, lines 20-30). Release controlling agent includes ethyl cellulose, and hydroxypropylmethyl cellulose acetate succinate in an amount of 0-30% (column 3, lines 5-42). The composition further comprises wax (column 4, lines 10-16). Fukui also teaches the amount of active agent is less than 30% by weight (column 4, lines 19-20). Table 1 shows example 20 uses 1% by weight of the active compound.

Fukui does not expressly teach the claimed amounts of the carrier ingredients, however, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). There're no unexpected and/or unusual results over the invention of Fukui. Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine suitable amounts of ingredients with a reasonable expectation of success because Fukui teaches a controlled release formulation for the same active agent, using the same hydrophobic

polymer, diluent, and microsphere forming agent, which having excellent controlled release property and high safety (column 1, lines 6-8; and column 2, lines 22-23).

Response to Arguments

Applicant's arguments filed 03/04/05 have been fully considered but they are not persuasive.

Applicant argues that the composition discussed in Fukui gives a different plasma concentration profile than the claimed formulation. In response to applicant's argument that the reference does not to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., plasma concentration profile) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Declaration under 37 CFR 1.132 filed 03/04/05 is insufficient to overcome the rejection of claims 1-5 based upon Vaghefi et al. as set forth in the last Office action because: the Declaration does not show evidence of criticality or unexpected results over Vaghefi. The Declaration shows the physical differences, for example, the microsphere of the present invention has rough outer surface indicating that all components including the active ingredient and excipients are uniformly mixed, while the smooth outer surface of the microsphere of Vaghefi indicates that no active ingredient and excipients are present in the outer surface of the microsphere. However, the Declaration fails to show any unexpected and/or unusual results between the

claimed microsphere and that of Vaghefi. What are the advantageous results in having the active ingredient and excipients present in the outer surface? Besides, the claims do not require the present of active ingredient in the outer surface of the microsphere.

The Declaration under 37 CFR 1.132 filed 03/04/05 is insufficient to overcome the rejection of claims 1-5 based upon Fukui et al. as set forth in the last Office action because: the Declaration does not show evidence of criticality or unexpected results over Fukui. The Declaration states that elevated temperature will cause acrylic acid polymers to become glue-like during granulation, and the lower concentration of aqueous controlling agent would not cause the glue-like condition during granulation. However, the Declaration fails to show any unexpected and/or unusual results between the claimed microsphere and that of Fukui. What is the detrimental effect in glue-like condition? Furthermore, it is noted that the recited claims are drawn to product claims, and the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Accordingly, it is the position of the examiner that the patentability of the claims does not depend on the elevated temperature during granulation.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al. us cited as of interest for the teaching of sustained release formulation comprising tamsulosin HCl.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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